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10/519,941	12/29/2004	Masaya Tanaka	0020-5615PUS1	5052
2292 7590 05/14/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
OSTRUP, CLINTON T				
ART UNIT		PAPER NUMBER		
3771				
NOTIFICATION DATE		DELIVERY MODE		
05/14/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/519,941

**Applicant(s)**

TANAKA, MASAYA

**Examiner**

CLINTON OSTRUP

**Art Unit**

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/2/10 & 2/3/10.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4, 6 and 13-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1, 2, 4, 6 and 13-15 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This Office Action is in response to the amendment filed February 2, 2010 and the supplemental amendment filed February 3, 2010. As directed by the amendment filed February 2, 2010, claims 1-2, 4, and 6 have been amended, claims 3, 5, and 7-12 are cancelled, and claims 13-14 have been added. As directed by the supplemental amendment filed February 3, 2010, claim 15 has been added. Thus, claims 1-2, 4, 6, and 13-15 are pending in this application.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4, 6 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339).

Regarding claim 1, Nishino discloses a carbon dioxide external administration device (figure 1) comprising: a sealing enclosure member (1) capable of sealing a body surface from outside air; the sealing enclosure member being capable of holding carbon dioxide gas within a sealed inside space; a supply means (2) for supplying carbon dioxide gas into an inside space of the sealing enclosure member; and an absorption aid (water) that is provided in the inside space of the sealing enclosure member, containing a carbon dioxide-dissolving medium (water) for dissolving carbon

dioxide gas, and dissolves carbon dioxide gas to assist transdermal or transmucosal absorption of the carbon dioxide. See: [0008-0015] and figure 1.

However, Nishino lacks the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate.

Tanaka et al teaches a carbon dioxide external administration device with a carbon dioxide absorption aid that contains a carbon dioxide dissolving medium in the form of an emulsion or a cream and said emulsion or cream comprising at least an oil or fat, a surfactant and water. See: Tanaka et al., See: col. 2, lines 36 - col. 9, line 57. Tanaka suggests the use of a viscous material containing **sodium alginate** (throughout disclosure (e.g. col. 2, line 67 and col. 7, lines 43-45)), examples (e.g. examples 1-79, 81-82, 85-99, 102, 104-105, 107, 109-140, 142, 145-175, 177, 180-196, 199-201, 204-208, 216-219, 226-242, 248-265, 271-287, 293-299) and claims (e.g. claims 1, 3, and 9) or **propylene glycol alginate** (col. 2, line 67 - col. 3, line 1 and col. 7, lines 43-45). See: col. 7, lines 43-46, Tables 1-25 and claims 1, 3, and 9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the absorption aid (water) of Nishino, by using an aqueous viscous gel composition as taught by Tanaka with alcohols having high vaporization temperatures and oils and fats in order to provide an absorption aid comprising the specific ingredients suggested by Tanaka, that would provide "improved skin comfort, usability, and the like of the composition by adding a perfume, color material, moisturizer, oily component..." See: Tanaka col. 9, lines 13-50

Regarding claim 4, Tanaka teaches incorporating carbon dioxide containing viscous compositions into a sheet for topically applying carbon dioxide gas to skin. See: col. 3, line 65 - col. 4, line 3; col. 12, lines 4-33; col. 43, lines 38 - col. 44, line 58.

Regarding claim 6, Nishino discloses a carbon dioxide external administration device with a sealing enclosure member (1 or 11) that is made from a flexible material having a shape holding ability (when inflated), an elastic and flexible material (it expands and contracts as it is inflated) formed into a shower cap or a boot.

Regarding claim 13, Tanaka suggests the use of a viscous material containing sodium carboxymethyl cellulose. See: col. 2, lines 58-59 and Tables 1-4, 7-10, 12-13, 15-25, which show numerous examples with sodium carboxymethyl cellulose.

Regarding claim 14, Tanaka suggests the use of a viscous material containing sodium dihydrogen phosphate. See: col. 3, line 30 and col. 9, lines 6-12.

4. Claim 2 and is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339) and further in view of Westwood (WO 98/173340).

The combined references disclose all the limitations of claim 2, except the carbon dioxide amount indicator being provided separately from the sealing enclosure member.

Westwood teaches a sealing enclosure member (10) with a valve (18) that would expand (open) when carbon dioxide is supplied into the sealing enclosure member (at least at a given pressure) and contracts (closes) when the amount of carbon dioxide decreases (when the pressure falls below the given pressure). See: figures 1-6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a valve, as taught by Westwood, to the boot device disclosed by the combined references, in order to determine when the optimal amount of carbon dioxide pressure is being applied to the user.

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339), as applied to claim 1 above, and further in view of Gedouin et al., (6,258,366). Regarding claim 1, Nishino in combination with Tanaka discloses a carbon dioxide external administration device (figure 1) comprising: a sealing enclosure member (1) capable of sealing a body surface from outside air; the sealing enclosure member being capable of holding carbon dioxide gas within a sealed inside space; a supply means (2) for supplying carbon dioxide gas into an inside space of the sealing enclosure member; and an absorption aid (water) that is provided in the inside space of the sealing enclosure member, containing a carbon dioxide-dissolving medium (water) for dissolving carbon dioxide gas, and dissolves carbon dioxide gas to assist transdermal or transmucosal absorption of the carbon dioxide. See: [0008-0015] and figure 1.

However, Nishino in combination lacks the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate but without the composition containing a carbonate.

Gedouin discloses a composition comprising depolymerized sodium alginate and teaches that it is beneficially applied to a user's skin to protect the skin of the wearer

from the harmful effects of atmospheric pollutants. The composition of Gedouin comprises depolymerized sodium alginate without a carbonate, and this composition is taught to protect the skin from harmful pollutants. See: abstract, col. 2, lines 1-8; col. 3, lines 12-22 and claims 1-3, 9, and 20.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the carbon dioxide absorption aid disclosed by the combined references, by using a sodium alginate aqueous composition without a carbonate, as taught by Gedouin, in order to form a device that promotes blood circulation while simultaneously protecting the skin from harmful pollutants.

#### ***Response to Arguments***

6. Applicant's arguments filed February 2, 2010 have been fully considered but they are not persuasive.

Applicant initially argues on page 4, last paragraph to page 5, last paragraph, that the present invention has advantages to those disclosed by Tanaka (6,689,339) in Example 299. Applicant then provides a synopsis of the finding found in the Declaration of Masaya Tanaka under 37 CFR 1.132. These arguments are not found convincing for the reasons set forth below in the response to the Declaration of Masaya Tanaka under 37 C.F.R. 1.132.

In response to applicant's arguments on page 6, first two paragraphs, against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

*Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the instant case, Nishino was used to teach all the limitations of the device, except the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate. As described above, Tanaka (6,689,339) teaches a carbon dioxide external administration device with a carbon dioxide absorption aid that contains a carbon dioxide dissolving medium in the form of an emulsion or a cream and said emulsion or cream comprising at least an oil or fat, a surfactant and water. See: Tanaka et al., See: col. 2, lines 36 - col. 9, line 57. Tanaka also suggests the use of a viscous material containing **sodium alginate** (throughout disclosure (e.g. col. 2, line 67 and col. 7, lines 43-45)), examples (e.g. examples 1-79, 81-82, 85-99, 102, 104-105, 107, 109-140, 142, 145-175, 177, 180-196, 199-201, 204-208, 216-219, 226-242, 248-265, 271-287, 293-299) and claims (e.g. claims 1, 3, and 9) or **propylene glycol alginate** (col. 2, line 67 - col. 3, line 1 and col. 7, lines 43-45). See: col. 7, lines 43-46, Tables 1-25 and claims 1, 3, and 9.

Thus, the rejection is based upon the combination of Nishino and Tanaka (6,689,339) and the examiner maintains that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the absorption aid (water) of Nishino, by using an aqueous viscous gel composition as taught by Tanaka with alcohols having high vaporization temperatures and oils and fats in order to provide an absorption aid comprising the specific ingredients suggested by Tanaka, that would provide "improved skin comfort, usability, and the like of the



composition by adding a perfume, color material, moisturizer, oily component..." See: Tanaka col. 9, lines 13-50.

Regarding applicant's argument that Nishino and Westwood both fail to make up for the deficiencies of Tanaka (6,689,339), applicant is respectfully reminded that Nishino is the primary reference and Tanaka was used to teach what was lacking in Nishino. In claims 1, 4 and 6 Nishino discloses all the claimed limitation of the device except the absorption aid. Tanaka (6,689,339) provides the missing carbon dioxide absorption aid and provides an excellent reason for replacing the carbon dioxide absorption aid of Nishino (water) with the carbon dioxide absorption aid of Tanaka (i.e. to provide "improved skin comfort, usability, and the like of the composition by adding a perfume, color material, moisturizer, oily component..." See: Tanaka col. 9, lines 13-50.

Therefore, applicant's arguments have not been found convincing and the rejection has been MAINTAINED.

***Response to the Declaration of Masaya Tanaka under 37 C.F.R. 1.132***

7. The Declaration of Masaya Tanaka under 37 CFR 1.132 filed February 2, 2010, is insufficient to overcome the rejection of claims 1-2, 4, 6 and the newly applied rejections of claims 13-15 as being unpatentable under 35 U.S.C. 103(a) as set forth above.

The declaration has not been found convincing because: It refer(s) only to Example 2 described on pages 25-26 of the specification and not to the individual claims of the application. Example 2 requires numerous embodiments that are not claimed for example, a "viscous material [was] prepared using 1.8 parts by weight of

sodium alginate and 1 part by weight of sodium carboxymethyl cellulose as thickeners, 0.2 part by weight of methylparaben as a preservative, and 97 parts by weight of purified water as water, and this viscous material was used as a carbon dioxide absorption aid 4." Moreover, unclaimed modifications including a "plastic glove", a "CO2 cylinder" and a "hand" were used to carry out the experiment, none of which are recited in the rejected claims. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Moreover, the Declaration of Masaya Tanaka at page 2, part 3, admits that the composition of Example 299 of 6,689,339 "is viscous" and "From this point of view, Example 299 is similar to the present invention."

Then, Masaya Tanaka describes vasodilatation being superior using the composition of Example 2 than with the composition of Example 299 of (6,689,339). However, Masaya Tanaka fails to relate the increased temperature and vasodilatation to the "carbon dioxide external administration device" as claimed. In fact, the increased vasodilatation could be based upon the properties of the composition, which, as described above, are not claimed.

Moreover, the rejection was based upon the combination of Nishino et al., (JP 07-171189 A) and further in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339) and Nishino teaches the device claimed, but lacks the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate. Therefore, to show unexpected results, a comparison of the claimed device, given its broadest reasonable interpretation, should be compared to the device of the

combined references. Therefore, the Declaration of Masaya Tanaka has not been found convincing and the rejections have been MAINTAINED and applied as described above.

As a final note, it appears the Declaration of Tanaka provides an admission that "Sodium alginate" and "Propylene glycol alginate" are substantial equivalents of one another, as Masaya Tanaka describes in the Declaration at the paragraph bridging pages 4 & 5 that:

"Incidentally, Sodium alginate was used in the above described experiment. However, even if Propylene glycol alginate is used instead of Sodium alginate, the result similar to that of the above described experiment may be obtained. The reason is as follows. That is, Propylene glycol alginate is an ester compound of Sodium alginate. Sodium alginate and Propylene glycol alginate are used as thickener in the field of cosmetics and have no difference in the nature from the viewpoint of thickener. In the field of food, particularly in the food having high calcium concentration, Sodium alginate tends to become gel, and therefore, Propylene glycol alginate is preferably used. However, the present invention is unrelated to calcium. Therefore, in the present invention, that is, in the field of cosmetics, Sodium alginate and Propylene glycol alginate can be preferably used and which thickener to use merely depends on user's taste."

Thus, given that 6,689,339 suggests the use of a viscous material containing **sodium alginate** (throughout disclosure (e.g. col. 2, line 67 and col. 7, lines 43-45)), examples (e.g. examples 1-79, 81-82, 85-99, 102, 104-105, 107, 109-140, 142, 145-175, 177, 180-196, 199-201, 204-208, 216-219, 226-242, 248-265, 271-287, 293-299) and claims (e.g. claims 1, 3, and 9) or **propylene glycol alginate** (col. 2, line 67 - col. 3, line 1 and col. 7, lines 43-45); it is reasonable to expect the composition of 6,689,339 to function in a similar manner when used with the device disclosed by Nishino, particularly given no particular amounts of Sodium alginate or Propylene glycol alginate are claimed in the instant application.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CLINTON OSTRUP** whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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